

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) P22022.00	
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____  Signature _____</p> <p>Typed or printed name _____</p>		<p>Application Number 10/672,009</p> <p>Filed 9-26-2003</p> <p>First Named Inventor Laurent Schaller</p> <p>Art Unit 3731</p> <p>Examiner Nguyen, Tuan Van</p>	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s).  Note: No more than five (5) pages may be provided.</p>			
<p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest.  See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  (Form PTO/SB/98)</p> <p><input checked="" type="checkbox"/> attorney or agent of record.  Registration number <u>59,862</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34.  Registration number if acting under 37 CFR 1.34 _____</p>		 Signature <u>Katrina A. Witschen</u> Typed or printed name <u>763-505-8418</u> Telephone number  Date	
<p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.  Submit multiple forms if more than one signature is required, see below.</p> <p><input type="checkbox"/> *Total of _____ forms are submitted.</p>			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.8. This collection is estimated to take 12 minutes to complete. The burden for this collection arises from completing a completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Schaller et. al.

Examiner: Nguyen, Tuan Van

Serial No.: 10/672,009

Group Art Unit: 3731

Filing Date: 9-26-2003

Docket No.: P22022.00

Title: SURGICAL CONNECTION APPARATUS AND METHODS

**MS After Final**

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

**PRE-APPEAL BRIEF REQUEST FOR REVIEW--ARGUMENTS**

Applicants request review of the final rejection of claims 1-33 in the above-identified application. These claims, as they appear in the Listing of the Claims on pages 2-6 of the Amendment and Response filed July 31, 2007 were rejected in the Final Office Action mailed September 26, 2007.

Claims 1-33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Arcia et. al. (U.S. Patent No. 6,358,258 "Arcia") in view of Miller et. al. (U.S. Patent No. 6,709,442 "Miller"). In particular, the Examiner asserts that "it would have been obvious to one of ordinary skill in the art to replace needle 270 and suture 272 of Arcia with hollow needle 54, clip 10, and pusher 52 as disclosed by Miller for two purposes: eliminating the tying knot because tying knot is time consuming and providing the advantage of the clip assume a shape that automatically applies to the layers of tissue an appropriate hemostatic compression which is relatively independent of tissue thickness as suggested by Miller." (Final Office Action, p. 6). This rejection is respectfully traversed.

First, neither the Arcia reference nor the Miller reference disclose *both* clips and barbs as provided in each of the independent claims (1, 17, 22 and 28) of the instant application. The Examiner alleges at Page 2 of the Final Office Action that the Nitinol needles 270 of Arcia are barbs. In support of this allegation, the Examiner states, "Arcia clearly discloses needles 270, wherein the needles piercing through the graft, therefore, the needles is equivalent to the barbs structure as claimed by the applicant." However, Arcia discloses the needles 270 as carrying sutures. Col. 9, line 58. Arcia discloses

needle 270 as purportedly being advanced through a first portion of a guide channel, through a graft body duct and through a second portion of a guide channel. Col. 10, lines 1-6. There is no mention or suggestion in Arcia as to how the needle 270 could be used as a barb nor does the Examiner set forth how the needle could be utilized as such. The assertion that the needle 270 can pierce through a graft and therefore is equivalent to a barb is not supported in the reference or in the knowledge generally available to one skilled in the art. Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727. Also, in the Examination Guidelines for Determining Obviousness in view of the KSR decision, the USPTO has noted that the key to supporting any rejection under §103 is the *clear articulation of the reason(s)* why the claimed invention would have been obvious.

Furthermore, Arcia does not disclose a plurality of self-closing clips and a plurality of barbs being separate from the clips, let alone clips that are ejectable from the support structure independently of the barbs as set forth in Claim 1. For argument's sake, if the needle 54 of Miller were to replace the needle 270 of Arcia as suggested by the Examiner, Applicants are unclear as to how the modification would read on Claim 1 since the Examiner has asserted that needle 270 of Arcia is a barb. Assuming the clip 10 of Miller were to be ejected out of needle 54, which the Examiner has suggested as a replacement for the "barb", it is unclear how clip 10 could be ejected *independently* of the alleged "barb" since it would be ejected out of the "barb".

In addition to the lack of disclosure of both clips and barbs in either the Miller or Arcia references, there is no incentive to modify the Arcia reference in the manner suggested by the Examiner. Specifically there is no reason or suggestion either in the references themselves or in the knowledge available to one skilled in the art to incorporate Miller's hollow needle 54, spring shaped fasteners 10 and pusher 52 into Arcia. For example, Arcia's suture can be tied into a loop to secure the graft to a second body duct. But no explanation of how Miller's fastener 10 would provide a similar loop

to secure the two tubular members together has been provided. Even assuming *arguendo* that Miller's needle 54 could replace needle 270 of Arcia, there is no explanation of how the fastener 10 of Miller, having now undergone the tortuous path of Arcia's needle 270, would fasten anything upon exit from the hollow needle. Miller merely discloses delivering spring shaped clips (e.g. fasteners 10) or suture element 236 through a tube. Even if Miller's clips were formed from memory shape material, it does not necessarily follow that they are self-closing clips as claimed by Applicants.

Furthermore, as Applicants explained in the Response and Amendment mailed July 31, 2007 at page 10, the Arcia embodiment illustrated in figures 8-14 and referenced in the Final Office Action does not teach deploying needles and sutures through channels 240 and 250 to secure the graft to a vessel because the suture guide channels are inoperative or not enabled for this purpose. No structure has been described to enable positioning second guide portion 250 inside the graft as shown in figure 11 of Arcia nor has the Examiner articulated how the Arcia embodiment could accomplish the stated purpose. Accordingly, Arcia should not be relied on as teaching deploying needles and sutures through guide channels to secure the graft to a vessel. Moreover, if the needle 54 of Miller were to replace needle 270 of Arcia, there remains the issue of the inoperability of Arcia. That is, there is no suggestion as to how the hollow needle of Miller could be passed from guide portion 240 through a graft and into second guide portion 250. The needle 54 of Miller does not remedy the deficiencies of Arcia.

The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. §103 *should be made explicit*. Thus, it remains necessary to identify some reason that would have led a person of ordinary skill in the art to modify the teachings of a reference in a particular manner in order to establish *prima facie* obviousness. In addition, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. M.P.E.P. 2143.01V. citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) Applicants respectfully submit that the Examiner has neither articulated nor made explicit either reasons or factors which would

**ARGUMENTS ACCOMPANYING PRE-APPEAL BRIEF REQUEST FOR REVIEW**

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Title: SURGICAL CONNECTION APPARATUS AND METHODS

have led a person of ordinary skill in the art to modify Arcia in the manner suggested. Also, the modifications proposed by the Examiner, as explained above, would render the Arcia device inoperable since there is no explanation of how the graft G could be joined to the body duct B by the replacement of needle 270 and suture 272 with needle 54 and clip 10 of Miller. Therefore, Applicants respectfully submit that *prima facie* obviousness has not been established. As discussed above, the cited art does not disclose or suggest all the limitations of claims 1-33. Withdrawal of the 35 U.S.C. §103(a) rejection of claims 1-33 is therefore respectfully requested.

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (763) 505-8418 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-2546.

Respectfully submitted,

Date: March 25, 2008

By Katrina A. Witschen  
Katrina A. Witschen  
Reg. No. 59,862  
Patent Counsel  
MEDTRONIC, INC.  
710 Medtronic Parkway  
Minneapolis, MN 55432  
Tel. 763-505-8418  
Fax. 763-505-8436  
Customer No. 27581